

REMARKS

Amendments

Claims 1-5, 7 and 10-34 have been canceled, claims 6, 9 and 35-39 have been amended, and claims 40-47 have been added. Upon entry of the amendment, claims 6, 8, 9 and 35-47 will be pending. The amendments do not constitute new matter and are supported throughout the specification, specifically on page 9, lines 22-26; Figure 2B; Example 2; and in the originally filed claims.

The foregoing amendments are made solely to expedite prosecution of the application and are not intended to limit the scope of the invention. Further, the amendments to the claims are made without prejudice to the pending or now canceled claims or to any subject matter pursued in a related application. The Applicant reserves the right to prosecute any canceled subject matter at a later time or in a later filed divisional, continuation, or continuation-in-part application.

Rejections

Rejections under 35 U.S.C. §§ 101/112 – 1st paragraph

The Examiner has maintained the rejection of claims 6, 8, 9, 23, 29-32 and 35-39 under 35 U.S.C. § 101 because the claimed invention is allegedly not supported by either a specific or substantial asserted utility or a well-established utility. In the Advisory Action, the Examiner concludes that (1) basic research such as studying properties of a claimed product is not a substantial utility; and (2) there is no correlation between the observed phenotype and a human disorder.

Applicant respectfully traverses the rejection. Applicant assumes that the August 31, 2004 Amendment was entered and that the arguments made therein are of record. The Examiner is respectfully requested to address the Applicant's points made in the present amendment as well as in the Amendment filed August 31, 2004. According to Patent Office guidelines, a rejection for lack of utility may not be imposed where an invention has a well-established utility or is useful for any particular practical purpose. The present invention satisfies either standard.

The present invention has a well-established utility since a person of ordinary skill in the art "would immediately appreciate why" knockout mice are useful. As set forth in the August 31, 2004 Amendment, the presently claimed transgenic mouse has been specifically ordered, bred and delivered to a pharmaceutical company for the purpose of investigating the gene's

function. The Examiner is respectfully requested to explain how the invention can have no utility when it is actually being used by one of skill in the art.

In addition, the present invention is useful for a particular practical purpose. Independent claim 6 is drawn to a transgenic mouse whose genome comprises a null FPR-RS4 allele, wherein the null allele comprises exogenous DNA. The claim encompasses a heterozygous mouse having a null allele where the null allele comprises exogenous DNA including a gene encoding lacZ (claim 47). The mouse is useful for studying FPR-RS4 gene expression (see Example 2), a utility which would be regarded as credible.

With regard to the Examiner's position (1), the transgenic mice are not being studied for the purpose of establishing a utility for the mouse itself. The mouse is being used as a research tool to study the function of the gene (see, e.g., MPEP § 2107.01, I). According to the Molecular Biology of the Cell (Albert, 4th ed., Garland Science (2002)), one of the leading textbooks in the field of molecular biology:

Extensive collaborative efforts are underway to generate comprehensive libraries of mutation in several model organisms including . . . the mouse. The ultimate goal in each case is to produce a collection of mutant strains in which every gene in the organism has either been systematically deleted, or altered such that it can be conditionally disrupted. Collections of this type will provide an invaluable tool for investigating gene function on a genomic scale.

(p. 543)(emphasis added). Transgenic mice are recognized by those skilled in the art as useful for investigating gene function. It is not understood by Applicant how the Examiner can argue a contrary position.

With regard to the Examiner's position (2), the Applicant submits that such a correlation is not required as the Applicant is claiming a mouse, not a method of treating humans. Applicant argued in the August 31, 2004 Amendment that the principles set forth in *In re Brana* should apply. The Examiner's views are respectfully solicited.

In summary, Applicant submits that the claimed transgenic mouse, regardless of any disclosed phenotypes, has inherent and well-established utility in the study of the function of the gene, and thus satisfies the utility requirement of section 101. Moreover, Applicant believes that the transgenic mice are useful for studying FPR-RS4 gene expression and are therefore useful for a specific practical purpose that would be readily understood by and considered credible by one of ordinary skill in the art.

It is submitted that the claims are currently in condition for allowance, and notice to that effect is respectfully requested. The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 13-2725.

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date


John E. Burke, Reg. No. 35,836
Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903
(303) 357-1637
(303) 357-1671 (fax)

